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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,156

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EXAMINER

DESAI, ANAND U

ART UNIT

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1656

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,156	Applicant(s) SATO ET AL.	
	Examiner ANAND U. DESAI	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-27, 54, 76, 78, 175, 195 and 198-214 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 11, 12, 27, 54, 76, 175 and 195 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 13, and 15-26 is/are allowed.
- 6) ☒ Claim(s) 78 and 198-214 is/are rejected.
- 7) ☒ Claim(s) 10 and 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is in response to the amendment filed on September 30, 2008. Claims 14, 32, 53, and 158 have been cancelled. New claims 200-214 have been added.
2. Claims 1-9, 11, 12, 27, 54, 76, 175, and 195 have been withdrawn previously.
3. Claims 10, 13, 15-26, 78, and 198-214 are currently pending and are under examination.

Withdrawal of Rejections

4. The rejection of claims 10, 13, 15-26, and 78 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to the claims.
5. The rejection of claim 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the cancellation of the claim.
6. The rejection of claims 78 and 198 under 35 U.S.C. 102(b) as being anticipated by Schatz (U.S. Patent 5,723,584) is withdrawn based on the amendment to the claims.
7. The rejection of claims 10, 13, and 15-17 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schatz (U.S. Patent 5,723,584) is withdrawn based on the amendment to the claims.
8. The rejection of claims 18-22 and 26 under 35 U.S.C. 103(a) as being unpatentable over Schatz (U.S. Patent 5,723,584) as applied to claims 10 and 13-17 above, and further in view of Reubi (U.S. Patent 6,312,661 B1) is withdrawn based on the amendment to the claims.
9. The rejection of claims 23-25 under 35 U.S.C. 103(a) as being unpatentable over Schatz (U.S. Patent 5,723,584) as applied to claims 10 and 13-17 above, and further in view of Wescott

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et al. (U.S. Patent 6,984,373 B2; previously cited) is withdrawn based on the amendment to the claims.

Pending Objections and Rejections

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 78, 198 and 199 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 11-20 of U.S. Patent No. 7,211,240 (Previously cited as US 2004/0018974 A1, SN 10/379,287 in office action mailed November 9, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a compound comprising a polypeptide sequence that is encompassed by claims 78, 198, and 199, and can bind to the same tyrosine kinase receptor, KDR, and the ligand-receptor complex, KDR/VEGF. SEQ ID

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NO: 18 of the issued U.S. Patent has 100% identity with SEQ ID NO: 308 of the instant application. The SEQ ID NO:'s are considered to be an obvious variant of each other, since Applicant state SEQ ID NO: 310 is a designated subset of the sequences for searching purposes (see Response to Restriction dated 9/18/2006, 2nd indented paragraph on page 2).

Response to Remarks

12. Applicants' state that it may remove the rejection with a terminal disclaimer when the claims are otherwise indicated as allowable.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 200-209, 213, and 214 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitagawa et al. (Chem. Pharm. Bull. 26(9): 2899-2903 (1978)) in view of Reubi (U.S. Patent 6,312,661 B1; previously cited).

Kitagawa et al. discloses the synthesis of a Substance P analog [8-Tyr] that comprises the sequence Gln-Gln-Phe-Tyr-Gly. Kitagawa et al. does not explicitly disclose the use of the selected radionuclide's, paramagnetic metal ions, or chelators, but does disclose the use of tyrosine containing peptides for radioimmunoassay (see page 2899, 2nd indented paragraph with reference to citations 12 and 13). Reubi discloses the use of radioactive halogen atoms being attached to a Tyr residue on peptide sequence or by labeling with a paramagnetic metal ion by means of a chelating group (see col. 4, line 48 through col. 7, line 52). The peptide disclosed by Kitagawa et al. does comprise a Tyr residue (see page 2900, Figure 1, [8-Tyr] analog sequence).

It would have been obvious to the person having ordinary skill in the art to use known techniques for labeling peptides, because the art has described the use of the selected radionuclide's, paramagnetic metal ions and chelators to label polypeptides. It is that the product is not one of innovation, but of ordinary skill and common sense using known techniques with anticipated success.

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17. Claims 210-212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitagawa et al. (Chem. Pharm. Bull. 26(9): 2899-2903 (1978)) in view of Reubi (U.S. Patent 6,312,661 B1; previously cited) as applied to claims 200-209, 213, and 214 above, and further in view of Wescott et al. (U.S. Patent 6,984,373 B2; previously cited).

Kitagawa et al. discloses the synthesis of a Substance P analog [8-Tyr] that comprises the sequence Gln-Gln-Phe-Tyr-Gly. Kitagawa et al. does not explicitly disclose the use of the ultrasound contrast agent label with a fluorinated gas. Wescott et al. discloses the labeling of peptides with a fluorinated gas (see col. 23, lines 18-30).

It would have been obvious to the person having ordinary skill in the art to use known techniques for labeling peptides, because the art has described the use of fluorinated gas as an ultrasound contrast agent with a labeled peptides. It is that the product is not one of innovation, but of ordinary skill and common sense using known techniques with anticipated success.

Claim Objections

18. Claims 10 and 78 are objected to because of the following informalities:

19. The amendment inserting an optional N-terminal or C-terminal amino acid or polypeptide leads to confusion for the last wherein clause. Is the last wherein clause referring to the optional N-terminal, C-terminal capping polypeptide or the isolated polypeptide being claimed? Suggest stating the N-terminal and C-terminal can be an amino acid or “peptides” as recited in claim 13. Appropriate correction is required.

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Conclusion

20. Claims 10, 13, and 15-26 are allowable over the prior art.
21. Claims 10 and 78 are objected.
22. Claims 200-214 are rejected.
23. This application contains claims 1-9, 11, 12, 27, 54, 76, 175, and 195 drawn to inventions nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 3, 2009

/ANAND U DESAI/

Primary Examiner, Art Unit 1656